K063124

510(K) SUMMARY

Integra MOZAIK™ Osteoconductive Scaffold

Submitter's name and address:
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA

JAN 19 2007

Contact person and telephone number:
Diana Bordon
Manager, Regulatory Affairs
Telephone: (609) 275-0500
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Date Summary was prepared:
December 11, 2006

Name of the device:

Proprietary Name:	Integra MOZAIK™ Osteoconductive Scaffold – Strip
Common Name:	Bone Void Filler
Classification Name:	Filler, Bone Void, Calcium Compound
Product Code:	MQV

Substantial Equivalence:
Integra MOZAIK Osteoconductive Scaffold - Strip is substantially equivalent in function and intended use to VITOSS® Scaffold Foam Bone Graft Matrix which has been cleared to market under Premarket Notification 510(k) K032288.

Device Description:
The Integra MOZAIK™ Osteoconductive Scaffold – Strip is a resorbable bone void filler made from a porous highly purified collagen matrix that has high purity tricalcium phosphate (TCP) granules dispersed throughout. The implant is provided sterile, non-pyrogenic, for single use in double peel packages.

The Integra MOZAIK Strip bone grafting construct is designed to facilitate the repair of bony defects. The matrix has a three dimensional trabecular network of pores that resembles the pore structure of human cancellous bone. The three dimensional pore structure of the Integra MOZAIK Strip quickly imbibes fluids, making it easy to mix with bone marrow aspirate or blood.

Integra MOZAIK Strip guides the regeneration of bone across a critical defect site into which the strip is implanted. New bone forms in apposition to the matrix surface when the graft is placed in direct contact with viable host bone. Ultimately the matrix is resorbed and remodeled into bone.

Intended Use:
The Integra MOZAIK Strip is intended for use as a bone void filler to fill voids or gaps of the skeletal system in the extremities, spine, and pelvis not intrinsic to the stability of the bony structure. Integra MOZAIK Strip is also indicated for use in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. Following placement in the bony void or gap (defect), Integra MOZAIK Strip is resorbed and replaced with bone during the healing process.

Performance Data:

Integra MOZAIK Strip has been demonstrated to support bone growth in an animal study, where it was ultimately resorbed and replaced by remodeled bone. These results, in conjunction with *in vitro* product characterization studies, performance testing and biocompatibility data demonstrate that Integra MOZAIK Osteoconductive Scaffold – Strip is as safe and effective as its predicate device.

Substantial Equivalence Comparison Chart

Feature	Integra MOZAIK™ Osteoconductive Scaffold – Strip	VITOSS® Foam *Strip* Bone Graft Material
Manufacturer	Integra LifeSciences Corp.	Orthovita, Inc., Malvern, PA
510(k)	K063124	K032288
Classification	MQV	MQV
Indications for Use	Integra MOZAIK™ Osteoconductive Scaffold - Strip is intended for use as a bone void filler to fill voids or gaps of the skeletal system in the extremities, spine, and pelvis not intrinsic to the stability of the bony structure. Integra MOZAIK Strip is also indicated for use in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. Following placement in the bony void or gap (defect), Integra MOZAIK is resorbed and replaced with bone during the healing process.	VITOSS Scaffold Foam Bone Graft Material is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. VITOSS Scaffold Foam is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. VITOSS Scaffold Foam should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously. VITOSS Scaffold Foam Bone Graft Material is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.
Target population	Individuals with bony defects resulting from surgery or trauma	Individuals with bony defects resulting from surgery or trauma
Design		
• **Physical structure**	Trabecular structure similar to cancellous bone in strip form.	Trabecular structure similar to cancellous bone in strips, cylinder and shape forms.
• **Pore Structure (range)**	12 – 350 microns	12 – 700 microns
Materials		
• **Chemical composition**	Calcium salt with Type I bovine collagen	Calcium salt with Type I bovine collagen
• **Mineral Phase**	β-Tricalcium phosphate $Ca_3(PO_4)_2$ per ASTM F1088	β-Tricalcium phosphate $Ca_3(PO_4)_2$ per ASTM F1088
Performance		
• **Osteoconductivity**	Osteoconductive	Osteoconductive
• **Mechanical Strength**	Does not impart mechanical strength to surgical site	Does not impart mechanical strength to surgical site
Sterility	Sterilized by 100% ethylene oxide gas, single use only	Sterilized by gamma irradiation, single use only
Biocompatibility	Biocompatible	Biocompatible
Anatomical location	Bony voids or gaps of the skeletal system i.e. the extremities, spine and pelvis	Bony voids or gaps of the skeletal system i.e. the extremities, spine and pelvis
Dosage Form(s)	15 cc (25 x 100 x 6mm)	25 x 50 x 4mm (5cc) 25 x 100 x 4mm (10cc) 25 x 50 x 8mm (10cc) 25 x 100 x 8mm (20cc) 75 x 100 x 4mm (30cc)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Integra LifeSciences Corporation
% Ms. Diana Bordon
Manager, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

JAN 19 2007

Re: K063124
Trade/Device Name: MOZAIK™ Osteoconductive Scaffold - Strips
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: December 12, 2006
Received: December 14, 2006

Dear Ms. Bordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bucchi
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Integra MOZAIK™ Osteoconductive Scaffold - Strip

Indications For Use: The Integra MOZAIK Osteoconductive Scaffold - Strip is intended for use as a bone void filler to fill voids or gaps of the skeletal system in the extremities, spine, and pelvis not intrinsic to the stability of the bony structure. Integra MOZAIK Strip is also indicated for use in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. Following placement in the bony void or gap (defect), Integra MOZAIK Strip is resorbed and replaced with bone during the healing process.

Prescription Use _X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063124